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Virginia Board of Pharmacy

NEWS

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Physician Assistants May Now Prescribe Schedule II Drugs

Effective July 1, 2007, physician assistants (PA) who have met criteria and have been approved by the Virginia Board of Medicine for prescriptive authority may prescribe drugs in Schedules II through VI that have been approved by the supervising medical practitioner or podiatrist. This is a limited, dependent authority similar to the nurse practitioner authority. Persons wishing to verify approval of prescriptive authority for a particular PA may call the Virginia Board of Medicine at 804/662-9929.

For a summary of all prescriptive authorities, please click on guidance document 110-8 located on the Virginia Board of Pharmacy's Web site at *www.dhp.state.va.us/pharmacy/pharmacy_guidelines.htm.*

Administering Vaccines

A pharmacist has legal authority to administer a vaccine via the following two methods: either pursuant to the receipt of a valid prescription instructing the pharmacist to dispense and administer a particular drug; or pursuant to a protocol approved by the Virginia Board of Nursing and authorized by a prescriber, to administer vaccines to adults as indicated by §54.1-3408, paragraph I of the Drug Control Act. Information that must be included in the protocol when submitted to the Board of Nursing is listed in Board of Nursing regulation 18VAC90-20-410, which may be accessed at *www.dhp.virginia.gov/nursing/leg/Nursing3-21-07.doc#_Toc107724270*. Please remember that if you intend to administer an adult vaccination program pursuant to a protocol, Board approval must first be obtained.

As with the administration of any drug, an understanding of possible adverse reactions is paramount and adequate precautions should be taken. For information on proper administering technique and suggested precautions when administering vaccines, please consult your professional organization or other programs that may offer additional training on this subject.

Storing Drugs in the Freezer

Maintaining drugs at the proper temperature, as indicated by the manufacturer, is crucial to maintaining drug stability. Virginia Board of Pharmacy regulation defines a controlled room temperature as between 68°F and 77°F; a cold temperature in a refrigerator is defined as between 36°F and 46°F; and a freezer is defined as thermostatically maintaining a temperature between -4°F and 14°F. Recently, it has come to the Board's attention that not all pharmacies may realize the proper temperature range for drugs stored in the freezer; therefore, there is concern for the drugs that require freezer storage such as Zostavax®.

Zostavax is indicated for prevention of herpes zoster (shingles) in individuals 60 years of age and older. Zostavax is stored frozen and should be reconstituted immediately upon removal from the freezer. The diluent should be stored separately at room temperature or in the refrigerator. The vaccine should be administered immediately after reconstitution, to minimize loss of potency; reconstituted vaccine that is not used within 30 minutes must be discarded. During shipment, to ensure that there is no loss of potency, the vaccine must be maintained at a temperature of -20°C (-4°F) or colder. In the pharmacy, Zostavax must be stored at an average temperature of -15°C (+5°F) or colder until it is reconstituted for injection. Any freezer, including frost-free, that has a **separate sealed freezer door** and reliably maintains an average temperature of -15°C (+5°F) or colder is acceptable for storing Zostavax, per the United States Food and Drug Administration (FDA).

Please note that Board inspectors will be checking for appropriate drug storage temperatures, and that small refrigerators with an inside freezer compartment are often noncompliant with the freezer standards. For more product approval information regarding Zostavax, please refer to the Web site for the FDA Center for Biologics Evaluation and Research at *www.fda.gov/cber/products/zostavax.htm.*

Prescription Monitoring Program Update

As of June 21, 2007, there are over 13.4 million records in the Prescription Monitoring Program (PMP) database. There are 895 registered users of the PMP Data Center, which includes 515 prescribers and 251 pharmacists. Each month, there is an increasing number of requests submitted for patient information. To date, PMP has fulfilled over 8,600 requests for prescription data compared to the approximately 6,300 requests received in 2006. Prescribers submit the majority of the requests for patient-specific prescription data, however, requests from pharmacists are also increasing.

In addition to providing prescription data to a registered user resulting from a request, PMP notifies prescribers through written communication of patients who meet a minimum threshold of criteria. The criteria generally includes the following: number

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FDA Issues Guidance on Glycerin Testing to Prevent DEG Poisoning

Spurred to action by repeated instances of diethylene glycol (DEG) poisoning, Food and Drug Administration (FDA) recently issued a guidance for industry entitled "Testing of Glycerin for Diethylene Glycol." This guidance provides recommendations on testing that will help pharmaceutical manufacturers, repackers, and other suppliers of glycerin, and pharmacists who engage in drug compounding, to avoid the use of glycerin that is contaminated with DEG and prevent incidents of DEG poisoning.

DEG contamination of glycerin can be detected by using specific analytical test procedures described in the United States Pharmacopeia monograph for glycerin, which quantifies the amount of DEG present at a detection level of 0.1%, as recommended by the interagency Diethylene Glycol Contamination Prevention Workshop of 1997. The guidance is available on the FDA Web site at *www.fda.gov/cder/guidance/7654fnl.htm.* FDA is accepting electronic comments on the guidance at *www.fda.gov/dockets/ecomments.*

Improperly Compounded Colchicine Blamed for Recent Deaths

Compounded colchicine that was 10 times as potent as labeled was responsible for two recent deaths in Oregon and Washington, the *Portland Tribune* reported on April 27, 2007. State officials are investigating the drug's role in a third death, also in Oregon. The drug was sent to a Portland, OR, clinic by ApothéCure, Inc, a Dallas, TX-based compounding pharmacy that distributes its drugs throughout the country. The two patients who died had received injections of colchicine as a treatment for back pain. Lab tests revealed that the colchicine administered in the two deaths had a potency of 4 mg/ml, rather than the 0.5 mg/ml stated on labels. According to Gary A. Schnabel, executive director of the Oregon State Board of Pharmacy, ApothéCure, a licensed Texas pharmacy, may be operating as a manufacturer. Both the Oregon Board and the Texas State Board of Pharmacy have opened investigations into the incident. The Texas Board advised ApothéCure to stop making colchicine; the company agreed, the *Portland Tribune* reported. On May 2, FDA announced the recall of all strengths, sizes, and lots of injectable colchicine compounded and sold by ApothéCure within the last year. The FDA MedWatch Safety summary on this issue is available at *www.fda.gov/medwatch/safety/2007/safety07.htm#Colchicine.*

New Podcasts Provide Emerging Drug Safety Information

FDA recently supplemented its print- and Web-based public health advisories with the launch of an audio broadcast service providing emerging drug safety information. The broadcasts, commonly known as podcasts, can be transmitted to personal computers and personal audio players. The service is part of FDA's ongoing effort to broaden and speed its communications on the safety of marketed medications when unexpected adverse events are reported to FDA. Since FDA launched the service in February 2007, broadcasts have addressed the potential hazards of local anesthetics used in hair removal; the voluntary market withdrawals of drugs to treat the symptoms of Parkinson's disease and irritable bowel syndrome; and serious adverse events associated with agents that reduce the need for blood transfusions in cancer patients. The broadcasts are available on the FDA Web site at *www.fda.gov/cder/drug/podcast/default.htm.*

Prevent Tragedies Caused by Syringe Tip Caps

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, then publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

Over the past several years, there have been a number of reports where children have swallowed or choked on hypodermic syringe caps that were overlooked by parents and left on the syringes administering the medication. In 2001, a 5-month-old child asphyxiated when a cap from a Becton Dickinson 3 ml hypodermic syringe ejected into his throat during medication administration. In this case, a pediatrician provided the parents with the hypodermic syringe (without the needle) to administer Vantin® (cefpodoxime) suspension. With the cap intact, the father inserted the syringe into the Vantin, pulled back the plunger, and the medication flowed into the syringe. To him, the cap appeared to be part of the syringe. When he placed the syringe containing the medication into the baby's mouth, the cap flew off and became lodged in his airway. The baby was taken to the hospital where a procedure was performed to remove the cap; however, he did not survive.

Despite these reports, the mother of a 9-month-old child recently notified the Institute for Safe Medication Practices about a near fatal experience involving her child. Her community pharmacist gave her a parenteral syringe (without the needle) to help her accurately measure and administer an oral rehydration liquid for her daughter. Unfortunately, the pharmacist's good intention resulted in patient harm. The mother was unaware that the syringe tip held a small, translucent cap; however, despite this, she was able to withdraw the oral liquid. Then as she administered the liquid, the cap on the end of the syringe ejected and became lodged in the child's throat, causing airway obstruction. Fortunately, the child recovered.

Although parenteral syringes are not designed for oral administration, health care practitioners may provide them to patients or caregivers to measure oral liquids without realizing how dangerous this practice may be. Some syringe

manufacturers place the small, translucent caps on parenteral syringes packaged without needles as a protective cover. However, practitioners may not realize the cap is there or may not inform patients or caregivers of the need for its removal prior to use. The danger arises due to the fact that the cap does not provide a good seal. Subsequently, medications can be drawn into many of these syringes without removing the caps. If not removed before administration, the force of pushing the plunger can eject the cap and cause it to lodge in a child's trachea.

Safe practice recommendations: Consider the following strategies to help protect your patients from tragedies caused by syringe tip caps.

- **Increase awareness.** Share this and previous errors with staff to illustrate why parenteral syringes should never be used for oral liquid medications. Show staff a video from FDA and ISMP highlighting this issue (access the video link at: *www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/transcript.cfm?show=3#6*).
- **Product availability.** Ensure that **oral** syringes (without caps) or other appropriate measuring devices are readily available for distribution or purchase at your practice site. Verify that the dosage can be accurately measured using the oral syringe. It may be necessary to keep a few different sizes on hand to ensure proper measurement of smaller doses.
- **Limit access.** If parenteral syringes must be stocked for use with injectable products, purchase syringes that are not packaged with the translucent caps to minimize the likelihood of this error.
- **Warning labels.** Add warning labels that state, "not for use with oral liquids" to boxes or storage bins containing parenteral syringes.
- **Educate patients and caregivers.** Provide education to patients and caregivers regarding proper use of an oral syringe (or other measuring device). Demonstrate how to measure and administer the dose and inform them about how to clean the device, if it is to be reused. Several years ago, Becton Dickinson voluntarily elected to package parenteral syringes without the small caps in response to this serious issue. However, since some manufacturers still include a cap on parenteral syringes, the danger of asphyxiation with the cap is still present. We have again contacted FDA to alert them about this problem. They have stated that they will be following up with each syringe manufacturer with the goal to get the syringe caps removed. At the very minimum, we believe that the packaging of parenteral syringes should be required to clearly state, "not for oral use" or "not for use with oral liquids."

New FDA Web Page Warns Against Buying Isotretinoin Online

FDA has launched a special Web page to warn consumers about the dangers of buying isotretinoin online. Improperly used, isotretinoin can cause severe side effects, including birth defects and serious mental health problems. The Web page, *www.fda.gov/buyonline/accutane*, is positioned as a search result on Internet search engines when consumers initiate an online search for the drug under any one of its four names (isotretinoin is sold under the brand name of Accutane® and in generic versions called Amnesteem™, Claravis™, and Sotret®). The Web page warns that the drug "should only be taken under the close supervision" of a physician and a pharmacist, and provides links to related information, including ways to check that drugs purchased online come from legitimate pharmacies.

To reduce risks, FDA and the manufacturers of isotretinoin have implemented a strict distribution program called iPLEDGE to ensure that women using isotretinoin do not become pregnant, and that women who are pregnant do not use isotretinoin. Isotretinoin is available only at pharmacies that are registered for this distribution program. Additionally, the distribution program is designed to prevent the sale of isotretinoin over the Internet. Dispensing must comply with the agency's risk management requirements.

Tampering Results in Misbranding of Ziagen as Combivir

GlaxoSmithKline and FDA warned health care professionals of an apparent third-party tampering that resulted in the misbranding of Ziagen® as Combivir® and employed counterfeit labels for Combivir tablets. Two 60-count misbranded bottles of Combivir tablets contained 300 mg tablets of Ziagen.

The counterfeit labels identified are Lot No. 6ZP9760 with expiration dates of April 2010 and April 2009. The incident appears to be isolated and limited in scope to one pharmacy in California.

Pharmacists are advised to immediately examine the contents of each bottle of Combivir in their pharmacies to confirm that the bottles contain the correct medication. If a bottle contains anything other than Combivir tablets, pharmacists are advised to notify the manufacturer.

The letter from GlaxoSmithKline and FDA, containing photos of actual Combivir and Ziagen tablets, is posted on the FDA Web site at *www.fda.gov/medwatch/safety/2007/Ziagen_Dear_RPh_03-29-2007.pdf*.

FDA Issues Halt on Manufacture, Distribution of Unapproved Suppository Drugs

FDA notified health care professionals and consumers that companies must stop manufacturing and distributing unapproved suppository drug products containing trimethobenzamide hydrochloride.

These products, used to treat nausea and vomiting in adults and children, have been marketed under various names, including Tigan®, Tebamide™, T-Gen, Trimazide, and Trimethobenz. Drugs containing trimethobenzamide in suppository form lack evidence of effectiveness. This action does not affect oral capsules and injectable products containing trimethobenzamide that have been approved by FDA.

FDA urges consumers currently using trimethobenzamide suppositories or who have questions or concerns to contact their health care professionals. Alternative products approved to effectively treat nausea and vomiting are available in a variety of forms.

The MedWatch safety summary and a link to the full press release are available at *www.fda.gov/medwatch/safety/2007/safety07.htm#trimethobenzamide*.

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of prescriptions filled for drugs in Schedules II, III, or IV to a particular patient within a minimum time frame; number of prescribers that have written prescriptions for drugs in Schedules II through IV for a particular patient within a minimum time frame; and the number of pharmacies that have dispensed drugs in Schedules II through IV for a particular patient within a minimum time frame. Once a patient reaches the established minimum threshold, the patient's prescribers are notified. The communication is intended to be a tool for the prescriber to use when treating the patient and is not intended to incriminate the patient or suggest mistreatment. Recently, over 100 patients were identified as exceeding the threshold for the number of pharmacies and the number of prescribers seen within one month. As a result, approximately 700 letters were sent to the corresponding prescribers for each of these patients. Surprisingly, PMP received approximately 20 calls from prescribers stating that they had not written certain prescriptions listed on their report. Possible explanations for the appearance of this data include the dispensing of fraudulent prescriptions or the assignment of the wrong prescriber to the prescription during the dispensing process. Therefore, please ensure that all prescriptions dispensed are valid prescriptions and that the appropriate prescriber's name is assigned to the prescription data. This will assist PMP in providing valuable and accurate information to prescribers.

For more information on the PMP and to learn how to request prescription information, visit *www.dhp.virginia.gov/dhp_programs/pmp/default.asp.*

Pharmacy Technician Duties

As stated in §54.1-3321 of the Drug Control Act, only the following persons shall perform the duties of a pharmacy technician: an individual registered with the Board as a pharmacy technician; an individual registered with the Board as a pharmacy intern for the purpose of gaining practical experience required to apply for licensure as a pharmacist; and an individual enrolled in a Board-approved pharmacy technician training program for the purpose of obtaining practical experience required for registration as a pharmacy technician, so long as such activities are directly monitored by a supervising pharmacist and do not exceed nine months from the date of enrollment. Please note that a national pharmacy technician certification does not immediately entitle the individual to perform the duties of a pharmacy technician in a pharmacy located in Virginia. This certified individual must first obtain registration from the Virginia Board of Pharmacy by submitting a pharmacy technician application to the Board prior to working as a pharmacy technician.

Upon being registered with the Board as a pharmacy technician, the following tasks may be performed:

- the entry of prescription information and drug history into a data system or other record-keeping system;
- the preparation of prescription labels or patient information;
- the removal of the drug to be dispensed from inventory;
- the counting, measuring, or compounding of the drug to be dispensed;
- the packaging and labeling of the drug to be dispensed and the repackaging thereof;
- the stocking or loading of automated dispensing devices or other devices used in the dispensing process; and
- the acceptance of refill authorization from a prescriber or his authorized agency, so long as there is no change to the original prescription.

Tasks that are not restricted to pharmacy technicians include the acceptance of a written prescription and the scanning of this prescription into an electronic database; the sole act of billing third-party insurances; and the stocking of shelves with prescription drugs within the prescription department upon receipt of a drug delivery.

Often as the result of Board inspections, cases are frequently opened on both the pharmacist-in-charge and the individual performing the duties of a pharmacy technician without proper registration or enrollment in a training program. While the Board has now been registering pharmacy technicians for approximately four years, the number of new cases continues to grow. Previously, the Board issued confidential consent agreements with no sanction imposed when resolving these cases. However, the Board will soon be considering imposing a sanction for this violation. All pharmacists should familiarize themselves with the process for becoming registered pharmacy technicians to be able to provide assistance. Additionally, pharmacists-in-charge are jointly held responsible with the individual for having individuals performing pharmacy technician tasks without proper registration, or properly seeking registration.

For more information on the registration process for a pharmacy technician visit the frequently asked questions section of the Board Web site at *www.dhp.virginia.gov/Pharmacy/pharmacy_faq.htm#TechRegistration.*

Board of Pharmacy is Moving

The Virginia Department of Health Professions (DHP), which encompasses 14 boards and various programs including the Board of Pharmacy, will operate from a new location on August 20, 2007. On August 16, DHP will close operations at noon to commence the moving process. The agency will remain closed on August 17, but will resume operations at 8:15 AM on Monday, August 20, 2007, from 9960 Mayland Drive, Suite 300, Richmond, VA 23233-1463. Telephone and fax numbers must change as a result of the move. The main telephone number for the Board will be 804/367-4456. The new fax number will be posted on the Web as soon as it is available.

All Web site functions will remain in operation during the move, ie, availability of applications, access to guidance documents and frequently asked questions, etc. However, communications via e-mail and telephone will be suspended starting at noon on August 16 and should resume by noon on August 20. It is the agency's desire to continue services with as little interruption as possible.

Board Officer Election Results

Elections for the offices of Board chairman and vice chairman for the period of July 1, 2007 through June 30, 2008, were held during the last full Board meeting on June 12, 2007. The Board voted unanimously to elect Bobby Ison to the office of Board chairman. Additionally, the Board voted unanimously to elect David C. Kozera to the office of vice chairman. Much appreciation is extended to John O. Beckner and Bobby Ison for their leadership and contributions during the past year as Board chairman and vice chairman, respectively.

The *Virginia Board of Pharmacy News* is published by the Virginia Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

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